Maine Dental Association

29 Association Drive, PO Box 215, Manchester, ME 04351-0215
telephone: 207-622-7900 fax: 207-622-6210

A Constituent of the American Dental Association

August 12, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20057

Ref. Docket # 01N-0067

Dear Sirs:

The Maine Dental Association ("MDA") wishes to submit the following comments regarding the Food and Drug Administration's ("FDA" or "the Agency") proposed rule on dental amalgam products and draft guidance document entitled, "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA."

1. The Maine Dental Association agrees with and supports the FDA's proposal to:
   - Issue a separate classification regulation for encapsulated amalgam alloy and dental mercury as a class II device with special controls;
   - Amend the existing classification for amalgam alloy, a class II preamendments device, by adding special controls; and
   - Reclassify from class I (general controls) to class II with special controls, dental mercury.

The FDA and other reputable scientific agencies have spent years studying the safety of dental amalgam. The conclusion has consistently been that there exists no meritorious scientific evidence to indicate that the use of dental amalgam causes any adverse health effects, except in rare instances where a person has an allergy to one component of the amalgam alloy. A uniform class II classification with special controls is appropriate to provide a reasonable assurance of safety of dental amalgam products for all dental patients and dental providers.

2. The MDA supports the comments submitted recently by the American Dental Association ("ADA") in their entirety. 01N-0067 C32

3. The MDA submits that the proposed rule should preempt state laws that conflict with the requirements encompassed by the proposed rule. As noted in the comments from the ADA, state laws regarding disclosure requirements for products that contain dental mercury or calling for the abolishment of dental amalgam products are directly at odds and incompatible with the federal requirements set forth by the FDA.

Thank you for the opportunity to provide comments on this matter.

Sincerely,

Karl P. Woods, DMD
President